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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,617	01/25/2001	Kim Sorensen	030307/0191	2002

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EXAMINER	
BURKHART, MICHAEL D	
ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/673,617	SORENSEN ET AL.	
	Examiner	Art Unit	
	Michael D. Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43, 44, 46-49, 51-53, 55, 56, 58, 59, 61, 63, 64, 66, 68, and 69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *46 and 53* is/are allowed.

6)☒ Claim(s) *43,44,47,48,51,52,56,58,59,61,63,64,66,68 and 69* is/are rejected.

7)☒ Claim(s) *49 and 55* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt and entry of the amendment dated 5/2/2007 is acknowledged. After entry of the amendment, claims 43, 44, 46-49, 51-53, 55, 56, 58, 59, 61, 63, 64, 66, 68, and 69 are pending and under examination.

New rejections of the claims are found below, hence, the finality of the previous Office Action is withdrawn.

Claim Objections

Claim 55 is objected to because of the following informalities: "auxothrophic" in line 3 should be "auxotrophic." Appropriate correction is required.

Regarding claims 51 and 52 below, the claims recite an intended use for the claimed product, a bacterium comprising a recombinant vector. The intended use is recited in lines 8-10 of claim 51, which states that the suppressor "suppresses a nonsense mutation that confers auxotrophy...and ...that is in a gene involved in the synthesis of pyrimidine nucleotides." Thus, the claim broadly reads on two types of bacterium comprising the vector: 1) those that also comprise the recited nonsense mutation; or, 2) those that do not. This is because the claimed suppressor, if present in the claimed bacterium, would be capable of suppressing any nonsense mutation arising from a TAG codon (i.e. is suppressed by an amber tRNA with a CUA anticodon). For this reason, a teaching in the prior art of the claimed bacterium comprising the claimed recombinant vector is considered to anticipate, or render obvious, claims 51 and 52.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 43, 44, 47, 48, 51, 52, 56, 58, 59, 61, 63, 64, 66, 68, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Dickely et al (WO95/10621, cited by applicants).

Dickely et al teach the isolation of an amber suppressor from *Lactococcus lactis* having a CUA anticodon (page 40, lines 9-27). Food-grade plasmids are disclosed that comprise the amber suppressor and a replicon from a lactic acid bacterium (page 13, first full ¶), examples of the food-grade vectors are indicated to be the pFG vectors found later in the specification (page 14, lines 2-3), and food-grade vectors are taught to only contain DNA of lactic acid bacterial origin (page 12, lines 8-12). Finally, the exemplified food grade vector (pFG1) does not encode

an antibiotic resistance gene (see Example 10, beginning on page 52). The amber suppressor may be under control of a regulatable promoter, which may be heterologous (page 16, line 30 - page 17, line 9). Desirable genes may be inserted into the vectors (page 14, first full ¶), such as phage lysins (page 18, lines 20-25), or genes that confer bacteriophage resistance (¶ linking pages 21-22). Isolated pure cultures of lactic acid bacterium comprising the disclosed vectors are found on page 15, lines 17 - 31. Acceptable carriers for the isolated cultures are disclosed on page 17, lines 20-31.

Methods of using the amber suppressor to suppress a nonsense mutation in a gene involved in the synthesis of purine nucleotides or general nucleotide resistance, i.e. a method of suppressing auxotrophy, are disclosed on pages 12 -13 and pages 21-22. Preferred genes that carry nonsense mutations are taught on page 56, and include genes involved in pyrimidine biosynthesis. 3

Claims 43, 44, 47, 48, 51, 52, 56, 58, 59, 61, 63, 64, 66, 68, and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Dickely et al (U.S. Patent 5,866,385, 102(e) date 12/5/1995).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived

from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Dickely et al teach the isolation of an amber suppressor from *Lactococcus lactis* having a CUA anticodon (Examples 4B and 4C, columns 21 and 22). Food-grade plasmids are disclosed that comprise the amber suppressor and a replicon from a lactic acid bacterium (column 7, lines 41-59), examples of the food-grade vectors are indicated to be the pFG vectors found later in the specification (column 8, lines 5-6), and food-grade vectors are taught to only contain DNA of lactic acid bacterial origin (column 7, lines 5-10). Finally, the exemplified food grade vector (pFG1) does not encode an antibiotic resistance gene (see Example 10, beginning in column 28). The amber suppressor may be under control of a regulatable promoter, which may be heterologous (column 9, lines 36 - 54). Desirable genes may be inserted into the vectors (column 8, lines 7- 36), such as phage lysins (column 10, lines 39-41), or genes that confer bacteriophage resistance (column 12, lines 18-29). Isolated pure cultures of lactic acid bacterium comprising the disclosed vectors are found in column 8, line 64 - column 9, line 3. Acceptable carriers for the isolated cultures are disclosed in column 9, line 65 - column 10, line 9.

Methods of using the amber suppressor to suppress a nonsense mutation in a gene involved in the synthesis of purine nucleotides or general nucleotide resistance, i.e. a method of suppressing auxotrophy, are disclosed in column 7, lines 21-40 and pages 21-22. Preferred genes that carry nonsense mutations are taught in column 30, lines 41-56, and include genes involved in pyrimidine biosynthesis.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 43, 44, 47, 48, 51, 52, 56, 58, 59, 61, 63, 64, 66, 68 and 69 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13, 14, 16-20, 28-30, 32-35, and 42-46 of U.S. Patent No. 5,866,385. Although the conflicting claims are not identical, they are not patentably distinct from each other because the lactic acid bacterium cultures and plasmids recited by the '385 claims comprise all the limitations of the instant claims. Claims 13, 14 and 16-20 of the '385 patent recite bacteria comprising a nonsense suppressor, which may be an amber suppressor isolated from a lactic acid bacterium, and may be on a non-chromosomal "replicon", considered to be recombinant vector, absent evidence to the contrary and in light of claims 42-44. The '385 specification defines an amber suppressor as having a CUA anticodon (column 5, lines 60-67). The nonsense suppressor may be under control of a regulatable promoter (claim 28), which may be heterologous with respect to the

nonsense suppressor (claim 29). The isolated pure cultures may also comprise a carrier (claim 30). Claims 32-35 recite a plasmid having the limitations recited above, capable of replicating in a lactic acid bacterium. The bacterial cultures may comprise a vector consisting of DNA from a lactic acid bacterium, a selectable marker, and a replication region. The selectable marker may be the suppressor gene, and the vector may be pFG1, in either case the vector does not comprise a gene coding for antibiotic resistance (claims 42-45, and definition of pFG1 in Example 10 of the specification). The vector may further comprise an inserted gene coding for a desired gene product (claim 46). Looking to the specification for guidance on the broadly recited genus of "desired gene product", it is noted that disclosed embodiments are phage lysins (column 10, lines 39-41) or genes that confer bacteriophage resistance (column 12, lines 18-29).

Conclusion

Claims 46 and 53 are allowed.

Claim 49 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart
Examiner
Art Unit 1633

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